

AD \_\_\_\_\_

Award Number: W81XWH-FEFA I €

TITLE: UÔÄ~ |ç^ Ä ÄÖ^c |{ ä ^Ä |^••~ |^Ä |& |Ä~ |} ^ |æäã Ä Ä@Ä~ d æä } oÄ [ ] ~ |æä }

PRINCIPAL INVESTIGATOR: Ö: ESä æÖ [ ~ |ä

CONTRACTING ORGANIZATION: Væ ] æXÖÜ^•^æ&Öä äÖä~ &æä } Ä [ ~ } äæä } Ä  
/æä ] æZÖÄH FG

REPORT DATE: U& ä^ |ÄFF

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

<b>REPORT DOCUMENTATION PAGE</b>				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. <b>PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.</b>					
1. REPORT DATE (DD-MM-YYYY) 01-10-2011		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 30 Sep 2010 - 29 Sep 2011	
4. TITLE AND SUBTITLE SCI Survey to Determine Pressure Ulcer Vulnerability in the Outpatient Population				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-10-1-0840	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Dr. Lisa Gould  E-Mail: lisa.gould@va.gov				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Tampa VA Research and Education Foundation Tampa, FL 33612				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Our preliminary hypothesis is that there are factors, biological and psychosocial, that increase or reduce vulnerability to PrUs among spinal cord injured persons. In the first phase of the study a data extraction tool was created based on variables that are thought to impact on PrU development. A retrospective review of 120 randomly sampled charts was conducted using this data extraction tool. The data obtained from this review will be used to refine the list of potential factors that increase or decrease vulnerability of patients with SCI to PrUs for use in a prospective survey of SCI patients coming to JAHVAH-SCI for their annual exam. To further understand the impact of physical characteristics on pressure ulcer development, high resolution ultrasound will be used to examine the tissue over the ischium of patients who have had many years without pressure ulcers compared to those who have had multiple, recurrent pressure ulcers. The data obtained from this research will be used to identify and stratify those factors, leading to the development of evidence-based risk assessment tools and customized interventions that will be tested in future randomized controlled trials.					
15. SUBJECT TERMS Pressure ulcer risk; spinal cord injury					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT  UU	18. NUMBER OF PAGES  11	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

## Table of Contents

	<u>Page</u>
Introduction.....	1
Body.....	2-4
Key Research Accomplishments.....	5
Reportable Outcomes.....	N/A
Conclusion.....	6
References.....	7
Appendices.....	8

**Introduction:**

Most published research that identifies risk factors for development and recurrence of Pressure Ulcers has been conducted in the nursing home elderly or in the acute phase of spinal cord injury. Studies of pressure ulcer risk and recurrence in the veteran SCI population has focused on patients who have already developed pressure ulcers. The goal of the proposed research is to perform an epidemiological and non-invasive anthropometric investigation of spinal cord injured persons with and without a history of pressure ulcers. Our preliminary hypothesis is that there are factors, biological and psychosocial that increase or reduce vulnerability to PrUs among spinal cord injured persons. The research will consist of a preliminary retrospective survey of outpatient SCI veterans. This sample will be utilized to refine the survey instruments that will be implemented in a larger prospective study of SCI persons coming to the James A Haley Spinal Cord System for their annual exam. Additionally a subset of patients will be selected for anthropometric studies that will provide insight into the impact of physical characteristics on pressure ulcer development. The data obtained from this research will be used to identify and stratify the factors that are different between patients who have never had a pressure ulcer and those who suffer from multiple ulcers, with emphasis on modifiable risk factors, leading to the development of evidence-based risk assessment tools and customized interventions that will be tested in future randomized controlled trials.

**Body:****Phase I Objectives/Specific Aims:**

The purpose of this study is to conduct a retrospective chart review. Specifically we intend to refine the list of potential factors that increase or decrease vulnerability of Patients with SCI to PrUs.

**Research Questions:**

1. What characteristics are associated with PrU development?
2. What characteristics protect from PrU development?
3. What demographic characteristics are predictive of PrU development?
4. What physical characteristics are predictive of PrU development?
5. What biological characteristics are predictive of PrU development?
6. What psychosocial characteristics are predictive of PrU development?

**Research Design:**

This study uses a retrospective cohort design to conduct the retrospective chart review.

**Inclusion/Exclusion Criteria:****Inclusion:**

Active Duty or Veteran patients with SCI that have completed their annual exam from the James A. Haley VA hospital between January 1, 2009 and December 31, 2009. Subjects may be male or female, age 18 or above. All races/ethnicities will have an equal opportunity to be included.

**Exclusion:**

Active duty or veterans with SCI lacking an annual exam from the James A. Haley VA hospital, or not completed between January 1, 2009 and December 31, 2009. Persons younger than 18 years old because the James A Haley VA hospital does not treat that age group.

The following disease states are excluded:

Active duty or veterans with an SCI due to terminal disease

Active duty or veterans with an SCI due to Multiple Sclerosis (MS)

Active duty or veterans with an SCI due to Amyotrophic Lateral Sclerosis (ALS)

**Research Procedures:**

A data extraction tool was created based on variables that are thought to impact on PrU development. This entailed multidisciplinary meetings and review of the existing literature. After obtaining VA R&D and IRB approval, a computer generated, random sample of 120 charts from more than 1400 patient charts of patients who completed

the annual exam at the James A Haley Spinal Cord Injury Center between January 1, 2009 and December 31, 2009, and who met all inclusion/exclusion criteria was conducted. The Access database (Appendix 1) was used to compile data from patient charts on variables, inclusive, but not limited to, the following list of factors:

*Demographics:* e.g. age, gender, marital status, living status, race/ethnicity

*Biological/Physical:* e.g. BMI, mobility, skin tone, spasticity, incontinence, renal, respiratory, and cardiac disease, diabetes, and nutritional status

*Psychosocial:* e.g. scholastic achievement, military achievement, financial support, social support

### **Phase I Preliminary Results:**

Preliminary analysis of this data set reveals that 37.8% have never had a pressure ulcer, 25% have had one, while 32% have had more than three pressure ulcers since their injury. Although 26% healed their pressure ulcers rapidly (0-3 months), 10% of the patients have never successfully healed their ulcer, contending with a chronic open wound. 74% of the population studied sustained their spinal cord injury more than 10 years ago, with 35.5% more than 30 years ago, indicating that this is indeed a study of chronic SCI. They are also a population with significant co-morbidities: 29.2% currently use tobacco, 37% of those smoke at least one pack per day; 22.7% have BMI >30 and 30% have been diagnosed with depression. The data set also identified a number of variables that are not easily extracted from the electronic medical record (either could not be found or were not present). Further analysis will stratify the data based on the number of pressure ulcers and identify which variables are lacking sufficient entries to be included in the data set.

### **Phase II**

The second phase of the study will be based on the retrospective analysis. The multidisciplinary team will review the data, refine the current data extraction tool and identify potential validated instruments that would augment the information that is not available in the electronic medical record. Results from the retrospective survey will be used to perform a power analysis based on key research questions and the sample size will be adjusted accordingly. A second IRB approval will be required for the prospective study.

### **Phase III (to be performed concurrent with Phase II)**

The anthropometric study will include use of the GE logiq-e musculoskeletal ultrasound to measure the depth of soft tissue over the ischial tuberosities before and after sitting for 30 minutes and 1 hour. Concurrent studies will include hyperspectral imaging of the skin over the ischial tuberosities to measure oxy and de-oxyhemoglobin and subepidermal moisture. These are all non-invasive measures and will take less than one minute to accomplish. No measurements to date have been possible with the patient seated, therefore rapid measurement prior to reperfusion is essential.

### **Difficulties encountered in the research to date:**

- 1) The time to obtain IRB approval for the retrospective study was unusually prolonged. Multiple factors accounted for this including unanticipated medical leave of one of our key personnel, medical leave of the main gatekeeper on the R&D, change in IRB personnel and being one of the first to utilize the electronic IRB submissions.
- 2) The data extraction from the electronic medical record was more labor intensive than anticipated. Particularly for patients with a history of pressure ulcers and surgical procedures, the charts were complex and the variables could not all be acquired from the annual exam. This necessitated that the data extractors delve into multiple provider notes and develop a list of rules to ensure consistency.
- 3) Change in key personnel. Two of the key personnel have relocated including the project manager and data manager. New personnel have been identified, added to the IRB protocol and provided access to all of the literature and files acquired to date.

**Key Research Accomplishments:**

A database of 120 SCI patients has been completed. Analysis is in progress and the first manuscript is in preparation.

**Conclusions:**

This research project is completing Phase I in preparation for Phase II. However, since this research was initiated, a number of projects have developed out of discussions of the team of researchers, substantiating the goal of the 'hypothesis development' initiative.

One of these projects was submitted to the HSR&D CREATE program. This is a program project grant that included multiple inter-related projects. Project #1 relied heavily upon our finding that retrospective chart review results in an incomplete data set. The team proposes to develop natural language processing (NLP) programs to reliably extract information about predictors from text in progress notes and store it as structured data. Project #3 proposed to prospectively determine the etiology and risk factors for PrU healing among community dwelling veterans with SCI, and to model the cost outcomes given selected interventions. Our prospective study and refined survey instruments will provide preliminary data for this project.

Additional projects emanating from our efforts include an analysis of osteomyelitis diagnosis and treatment with plans to submit a proposed algorithm to the SCI-QUERI' (SCI-Quality Enhancement Research Initiative), a submission to NIH for proteomic analysis of peri-wound biomarkers, and a telehealth initiative to provide home education to SCI veterans as a pressure ulcer prevention strategy.

**References:**

- Bates-Jensen BM, Guihan M, Garber SL, Chin AS, Burns SP. Characteristics of recurrent pressure ulcers in veterans with spinal cord injury. *J Spinal Cord Med* 2009;32(1):34-42.
- Garber SL, Rintala DH. Pressure ulcers in veterans with spinal cord injury: a retrospective study. *J Rehabil Res Dev* 2003 ;40(5):433-41.
- Aoi N, Yoshimura K, Kadono T, Nakagami G, Iizuka S, Higashino T, et al. Ultrasound assessment of deep tissue injury in pressure ulcers: possible prediction of pressure ulcer progression. *Plast Reconstr Surg* 2009;124(2):540-50.
- Henzel MK, Bogie KM, Guihan M, Ho CH. Guest Editorial: Pressure ulcer management and research priorities for patients with spinal cord injury: Consensus opinion from SCI QUERI Expert Panel on Pressure Ulcer Research Implementation. *J Rehabil Res Dev*. 2011;48(3):xi-xxxii.

ID: <input type="text" value="1"/> Enter Patient ID # (1-120)		<b>BOWEL MANAGEMENT</b>		<b>SUBSTANCE USE</b>	
YrOB: <input type="text"/>	GENDER: <input type="text"/>	BOWEL CONTINENT: <input type="text"/>	ALCOHOL: <input type="text"/>	PAST HX: <input type="text"/>	CURR USE: <input type="text"/>
AGE: <input type="text"/>	MARITAL STATUS: <input type="text"/>	COLOSTOMY: <input type="text"/>	AMPHETIMINES: <input type="text"/>		
Feet: <input type="text"/> Inches: <input type="text"/>	EDUC LEVEL: <input type="text"/>	BOWEL PRGM TYPE: <input type="text"/>	COCAINE: <input type="text"/>		
HT: <input type="text"/>	RACE: <input type="text"/>	BOWEL PRGM LOC: <input type="text"/>	CRACK: <input type="text"/>		
WT: <input type="text"/> BMI: <input type="text"/>	ETHNICITY: <input type="text"/>	BOWEL PRGM FREQ: <input type="text"/>	HALLUCINOGENS: <input type="text"/>		
EVIDENCE OF A CAREGIVER? <input type="text"/>	Days per Week: <input type="text"/> Hrs per Day: <input type="text"/>	# HRS PER TREATMENT: <input type="text"/>	HEROIN: <input type="text"/>		
IF YES, CAREGIVER STATUS?: <input type="text"/>			INHALANTS: <input type="text"/>		
<b>INJURY</b>		<b>BLADDER MANAGEMENT</b>		<b>COGNITIVE FUNCTION</b>	
MECHANISM: <input type="text"/>		BLADDER CONTINENT: <input type="text"/>	MENTAL STATUS: <input type="text"/>		
LEVEL(ASIA): <input type="text"/>		INDEWELLING CATHETER: <input type="text"/>	ANXIETY: <input type="radio"/>	DEPRESSION: <input type="radio"/>	
DAYS IN HOSP: <input type="text"/> DAYS IN REHAB: <input type="text"/> DAYS IN HOSP IN PAST YEAR: <input type="text"/>		CONDOM CATHETER: <input type="text"/>	BIPOLAR: <input type="radio"/>	PERSONALITY DO: <input type="radio"/>	
MOBILITY: <input type="text"/>		INTERMITTENT CATHETE: <input type="text"/>	BRAIN DMG-SURG: <input type="radio"/>	PTSD/ADJUST: <input type="radio"/>	
If "Power W/C", what type? <input type="text"/>		SUPRAPUBIC CATHETER: <input type="text"/>	DEMENTIA: <input type="radio"/>	SCHIZ/DELUS: <input type="radio"/>	
If "Bed Mobility", is there independent ability to <input type="text"/>		DOES CATHETER LEAK? <input type="text"/>			
FIM SCORE: <input type="text"/>		DIVERSION THERAPY: <input type="text"/>			
<b>SUPPORT SURFACES</b>		<b>PHYSICAL HEALTH</b>		<b>PRESSURE ULCER HX</b>	
BED OVERLAY: <input type="text"/>	ALBUMIN: <input type="text"/>	SPASTICITY: <input type="text"/>	# DAYS TO 1ST PU SINCE INJURY: <input type="text"/>		
W/C CUSHION: <input type="text"/>	PRE-ALBUMIN: <input type="text"/>	IF YES, MEDICATED?: <input type="text"/>	# PUs SINCE INJURY: <input type="text"/>		
TRANSPORT SEAT CUSHION: <input type="text"/>	HGB: <input type="text"/>	CONTRACTURES: <input type="text"/>	AVG. LENGTH TO HEAL PU: <input type="text"/>		
	HBA1C: <input type="text"/>	IF YES, SEVERITY?: <input type="text"/>	SURGERY NEEDED FOR PUs: <input type="text"/>		
<b>CAREER AND EMPLOYMENT STATUS</b>		<b>TOBACCO USE</b>		<b>PRESSURE ULCER LOCATIO</b>	
CAREER PRIOR TO ACCIDENT: <input type="text"/>		PAIN LEVEL 1-10: <input type="text"/>	HEELS: <input type="text"/>	TROCHANTER: <input type="text"/>	
CAREER AFTER ACCIDENT: <input type="text"/>			ISCHIAM: <input type="text"/>	SACRUM: <input type="text"/>	
CURRENT EMPLOYMENT STATUS: <input type="text"/>			OTHER: <input type="text"/>	OTHER: <input type="text"/>	
% SERVICE CONNECTED: <input type="text"/>					
<b>TRANSPORTATION TO PCP</b>					
TYPE OF TRANSPORTATION: <input type="text"/>		PAST HX: <input type="text"/> #Pack Yrs: <input type="text"/>			
TRANS. HAS ACCOMMODATING CHAIR?: <input type="text"/>		CURR USE: <input type="text"/> #Pack/Days: <input type="text"/>			